IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	
Plaintiffs,	Civil Action No. 1:08-07231
v.	Consolidated with Civil Action No. 1:09-cv-6053
APOTEX INC. and APOTEX CORP.,	Judge Robert M. Dow Jr.
Defendants.	Magistrate Judge Martin C. Ashman

REPLY MEMORANDUM IN SUPPORT OF
APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY

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Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this reply in support of their motion to compel discovery from Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company and Warner Lambert Company LLC (collectively, "Pfizer").

INTRODUCTION

In its opposition to Apotex's motion to compel (Dkt. Item No. ("D.I.") 157), Pfizer propounds numerous inaccurate and potentially misleading arguments in an attempt to improperly shield from discovery documents that are clearly relevant to the claims and defenses raised in this action. The Court can and should reject each of Pfizer's baseless arguments on at least the following grounds:

1. Regardless of whether Pfizer's settlement with Ranbaxy Laboratories Ltd. and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") addressed other disputes between those two parties, including any litigation involving the combination product Caduet®, Ranbaxy had every incentive to go to market with its generic atorvastatin tablets on March 24, 2010, after defeating Pfizer's U.S. Patent No. 5,273,995 ("the '995 patent"), and the fact that Pfizer was able to keep Ranbaxy off the market for an additional twenty (20) months after the date Ranbaxy would have otherwise been able to enter the market is relevant to numerous claims and defenses raised in this case;

2. Any purported "commercial success" Pfizer "established" in its litigation with Ranbaxy—which involved a patent not at issue in this case (U.S. Patent No. 4,681,893 ("the '893 patent")) and therefore different considerations—is not binding on this case, and Apotex is entitled to challenge Pfizer's claims of purported commercial success and whether any of it is tied to the '667 patent, which was ***not*** established in the *Pfizer v. Ranbaxy* cases. Further, even if Pfizer does not intend to rely upon licensing to show non-obviousness, it has nonetheless confirmed that it will rely on purported "commercial success" for Lipitor®, and any license contained in the various settlement agreement would be automatically and inherently relevant to any claim of commercial success and whether that purported commercial success is tied to the '667 patent, as it is required to be for Pfizer to rely upon it;

3. Moreover, the third-party generic atorvastatin agreements Apotex seeks are potentially relevant to purported commercial success regardless of whether they contain a license because the settlement agreements may have included a stipulation by Ranbaxy as to the non-obviousness of the '667 patent and/or as to

the purported commercial success of Lipitor® because of the '667 patent.

4. Pfizer cannot cite to one Seventh Circuit or Northern District of Illinois case supporting its settlement privilege argument, because none exists, and Pfizer's attempt to distinguish the Seventh Circuit's *In re General Motors Corp. Engine Interchange Litigation*, 594 F.2d 1106, 1124 (7th Cir. 1979) fails, as the court there expressly rejected such a privilege;

5. Pfizer has expressed its intention to appeal Judge Dow's denial of its motion to dismiss Apotex's counterclaim counts directed to U.S. Patent Nos. 5,686,104 ("the '104 patent"), 5,969,156 ("the '156 patent"), and/or 6,126,971 ("the '971 patent"), the three later-expiring Lipitor® patents, (*see* D.I. 160, Pl. Pfizer's Reply ¶17), ***and, on July 21, 2010, has moved this Court again*** for dismissal of Apotex's Counterclaim Counts directed to the '104 and '971 patents (D.I. 161, Pl. Pfizer's Mot. to Dismiss Counts III, IV and VIII of Def. Apotex's Countercls. Pursuant to FED. R. CIV. P. 12(b)(1) ("Pfizer's Second Mot. to Dismiss")); therefore, any settlement agreements Pfizer has entered into with other ANDA-filers should be produced because they most certainly involved those patents—patents that Pfizer misleadingly claimed posed no threat to Apotex or any other ANDA-filer;

6. Pfizer's reference to press releases regarding the settlement it reached with Ranbaxy in an attempt to undercut Apotex's patent misuse defense misses the point of discovery—Apotex is entitled to discovery on third-party generic atorvastatin agreements in order to develop any patent misuse defense that may exist that Apotex did not know about at the time it answered the First Amended Complaint in this action; such a patent misuse defense may exist if Ranbaxy was coerced into staying off the market under threat of another suit on the '995 patent or a suit on the yet to issue (as of the date of the agreement) '667 patent, for the purpose of delaying the entry of competing generic atorvastatin products, *see Key Pharms., Inc. v. ESI-Lederle, Inc.*, No. CIV. A. 96-1219, 1997 WL 560131, at *2-4 (E.D. Pa. Aug. 29, 1997);

7. Pfizer's claims of prejudice are unfounded because, as pointed out in Apotex's opening brief, any third-party generic atorvastatin agreements produced by Pfizer will be reviewed only by Apotex's outside litigation counsel, and will not be accessible to Apotex itself;

8. Pfizer misconstrues the plain language of 35 U.S.C. § 271(e)(4), the infringement remedy provision of the Patent Statute for Hatch-Waxman cases, which sets apart and distinguishes the resetting of any effective approval date for the infringing ANDA from injunctive relief, which "***may be granted against the infringer***," (35 U.S.C. § 271(e)(4)(B) (emphasis added));

9. Pfizer has prayed for permanent injunctive relief for infringement of the '667 patent, and therefore any documents on Pfizer's anticipated reaction to generic entry would be relevant to irreparable harm which it would be required to

> show upon a finding of infringement by the Court in this case, regardless of whether those documents speak to actions to be taken after the '667 patent has expired; and
>
> 10. The generic entry documents would also be relevant to purported commercial success. *See Orion Corp. v. Sun Pharm. Indus. Ltd.*, Nos. CIV.A 07-5436(MLC), CIV.A 08-5545(MLC), 2010 WL 686545, at *7-8 (D.N.J. Feb. 22, 2010) (holding that "information represent[ing] . . . possible generic market entry scenarios[,]" is relevant to commercial success and granting motion to compel production of the same).

For at least the foregoing reasons, more fully explained below, the third-party generic atorvastatin agreements and generic entry documents are clearly relevant to this litigation and, therefore, Apotex respectfully requests that Pfizer be ordered to produce these documents.

ARGUMENT

I. Ranbaxy's Decision to Delay Marketing Its Generic Atorvastatin Tablets Is Highly Relevant to Numerous Claims and Defenses in This Case.

Pfizer asserts that the "settlement [with Ranbaxy] involved multiple unrelated products (e.g., Accupril) and multiple patent disputes worldwide." (D.I. 157, Pfizer Opp. at 10). Regardless of whether Pfizer's settlement with Ranbaxy addressed other patent disputes, including any litigation involving the combinatorial product Caduet®, there was, nonetheless, a significant financial incentive for Ranbaxy to enter the generic atorvastatin tablets market on March 24, 2010, after defeating the '995 patent. Ranbaxy, however, stayed off the market for an additional 20 months after expiration of the '667 patent. Ranbaxy's decision to delay market entry is relevant to numerous claims and defenses raised in this case. The specifics of these third-party generic atorvastatin agreements will reveal much about what role the '667 patent played in allowing Pfizer to delay Ranbaxy's market entry. Most significantly, these third-party generic atorvastatin agreements are relevant to any alleged secondary considerations of non-obviousness, which Pfizer has already indicated it intends to rely upon here. (D.I. 149-8, July 9, 2010 Declaration of Andrew M. Alul, Esq. ("Alul Decl.") Decl. Ex. H). Specifically, as stated in

Apotex's opening brief, the secondary considerations that these agreements will bear most heavily upon include licensing and purported commercial success.

With regard to licensing, it is highly relevant whether the settlement and licensing terms are tied directly to the claimed aspects of the '667 patent or, instead, whether a host of other factors completely separate and apart from the clamed aspects of the '667 patent drove the agreements. As stated above, Pfizer has already admitted that its settlement with Ranbaxy involved multiple unrelated products and multiple other patent disputes. (D.I. 157, Pfizer Opp. at 10). Pfizer understandably, however, would like to leave it at that and attempts to do the same by indicating that it will not rely on licensing as an alleged secondary consideration supporting non-obviousness. This tactic on the part of Pfizer must fail, however. The point is that there were settlement agreements directly involving the '667 patent and that may—or may not—have included a license for Ranbaxy to make and use (but not market) atorvastatin prior to the expiration of the '667 patent. The lack of any license granted in the settlement agreement may arguably support obviousness of the '667 patent. Having already indicated that it intends to proffer evidence of purported secondary considerations, Pfizer should not be permitted to cherry pick only the evidence of secondary considerations that allegedly weighs in its favor and hide from that which does not.

Further, as discussed below, the third-party generic atorvastatin agreements are relevant to the purported "commercial success" secondary consideration. These third-party generic atorvastatin agreements, therefore, must be produced. See, e.g., *West v. Jewelry Innovations Inc.*, No. C07-01812 JF (HRL), 2009 WL 668695, at *1-2 (N.D. Cal. Mar. 13, 2009) (granting accused infringer's motion to compel patentee to produce unredacted versions of all settlement and licensing agreements relating to the asserted patents); *Bd. of Tr. of Leland Stanford Junior*

Univ. v. Tyco Int'l Ltd., 253 F.R.D. 521, 522-23 (C.D. Cal. 2008) (granting accused infringer's motion to compel patentee to produce settlement agreement with a third-party, who was also an accused infringer). The bottom line is that Pfizer cannot seriously contest the relevance of these documents, or at the very least, that such documents could lead to the discovery of other relevant evidence.

II. The Third-Party Generic Atorvastatin Agreements and Generic Entry Documents Are Relevant to Secondary Considerations Aside from Whether Pfizer Intends to Rely on Licensing.

In its Opposition, Pfizer argues that it "has already established the commercial and medical success of Lipitor® at trial in [the Ranbaxy litigations]." (D.I. 157, Pfizer Opp. at 6). This is nonsense. Commercial success is not assessed in a vacuum. Nor is anything established in that case somehow binding here. Rather, in order to establish that a product is commercially successful in a way meaningful to the secondary considerations analysis, the patentee must demonstrate a nexus between the purported commercial success and the claimed invention. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983). The Ranbaxy litigations involved a different patent, which is not at issue in this case – the '893 patent. The issue in this case is whether there exists a sufficient nexus between any alleged commercial success of Lipitor® and the '667 patent. This issue was not decided, or even addressed, in the Ranbaxy litigations. The precise contours of all settlement and licensing agreements between Pfizer and Ranbaxy (as well as Cobalt and Teva) are clearly relevant to any purported commercial success and whether that success is tied to the claimed aspects of the '667 patent. For instance, the settlement agreement may have included a stipulation by Ranbaxy as to the non-obviousness of the '667 patent and/or as to the commercial success of Lipitor® because of the '667 patent. Also relevant to the commercial success issue are the generic entry documents

Apotex seeks because such documents contain sales and market share projections, marketing plans, life-cycle plans and other pertinent information relating to commercial aspects of Lipitor®, including how the product has performed compared to its competitors. See *Orion*, 2010 WL 686545, at *7-8 (holding that "information represent[ing] . . . possible generic market entry scenarios[,]" is relevant to commercial success and granting motion to compel production of the same).

III. Prevailing Seventh Circuit Case Law Does Not Establish a "Settlement Privilege."

Pfizer cannot cite to one Seventh Circuit or Northern District of Illinois case supporting its "settlement privilege" argument, because none exists. To the contrary, the Seventh Circuit's decision in *In re General Motors Corp.*, 594 F.2d 1106, 1124 (7th Cir. 1979), expressly rejected such a privilege. In an apparent admission that In re General Motors Corp. does in fact run directly counter to any claim that a "settlement privilege" exists, particularly in the Seventh Circuit, Pfizer attempts to distinguish the case by asserting that it was a class action implicating Rule 23(e). (D.I. 157, Pfizer Opp. at 8-9). On this basis, Pfizer concludes that In re General Motors Corp. is not dispositive here. (D.I. 157, Pfizer Opp. at 9). Judge Wood's language in that opinion, however, is unambiguous. In fact, the Court in that opinion does not even recognize any sort of "settlement privilege" as such, instead referring to the fact that neither party in that case had argued that information regarding settlement is protected by "some form of [settlement] privilege." *In re General Motors Corp.*, 594 F.2d at 1124, n.20. The Court expressly stated that invocation of any such privilege could only be satisfied by demonstration that the information concerning settlement qualified for protection as attorney work product and/or fell within the scope of the attorney-client privilege. *Id*. ("Although particular documents or discussions [concerning settlement] conceivably could be immune from discovery as attorney

work product or as privileged attorney-client communications, the existence of such privileges is best determined in the context of particular demands for discovery."). As to any potential or alleged chilling effect on the free flow of information during settlement negotiations, the opinion states: "To the extent such inquiry discourages settlement, it should only discourage those negotiated in circumstances so irregular as to cast substantial doubt on their fairness." *Id*. The foregoing language from In re General Motors Corp. leaves no uncertainty as to where the Seventh Circuit stands on the issue of the existence of a "settlement privilege" as an independent grounds upon which to shield documents and information from discovery – there is no such privilege. A number of other courts have likewise refused to acknowledge such a "settlement privilege." *See, e.g., Matsushita Elec. Indus. Co. v. Mediatek, Inc.*, No. C-05-3148 MMC (JCS), 2007 WL 963975, at *4, *6 (N.D. Cal. Mar. 30, 2007) (holding that there exists no "federal settlement privilege"; and also characterizing the holding in In re General Motors Corp. as a rejection of a "settlement privilege").

IV. The Third-Party Generic Atorvastatin Agreements Are Relevant to Pfizer's Motion to Dismiss.

Pfizer argues that, to the extent any third-party generic atorvastatin agreements are relevant to its motion to dismiss Apotex's counterclaim counts directed to the '104 patent, the '156 patent, and the '971 patent (the three later-expiring Lipitor® patents), such relevance has now been mooted given that Pfizer's motion to dismiss has already been decided. (D.I. 157, Pfizer Opp. at 12). The fact that Judge Dow already decided Pfizer's motion, however, does not deprive the third-party generic atorvastatin agreements of their relevance. Pfizer has expressed an intention to appeal Judge Dow's denial of its motion to dismiss. (*See* D.I. 160, Pl. Pfizer's Reply ¶17). Moreover, ***on July 21, 2010, Pfizer moved this Court again*** for dismissal of Apotex's Counterclaim Counts directed to the '104 and '971 patents (D.I. 161, Pl. Pfizer's

Second Mot. to Dismiss). As such, the third-party generic atorvastatin agreements should be produced so that any available information in them regarding the three later-expiring Lipitor® patents can be used by Apotex before this Court or the Federal Circuit to justify subject matter jurisdiction over its counterclaims.

For the reasons set forth in Apotex's opening brief, all third-party generic atorvastatin agreements should be produced because they most certainly involved the '104 patent, the '156 patent, and/or the '971 patent and, therefore, directly bear on Apotex's counterclaims relating to these patents and Pfizer's motions to dismiss.

V. The Facts of the Case Established to Date Indicate Potential Patent Misuse by Pfizer, Which Apotex Is Entitled to Pursue Through Discovery.

The '667 patent is a reissue of the '995 patent, which Ranbaxy defeated in litigation. *See Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006). As set forth in detail in Apotex's opening brief, Apotex is entitled to discovery relating to the issue of whether Pfizer has misused the '667 patent in an anti-competitive way. Pfizer argues that Apotex has not pleaded patent misuse specifically as an affirmative defense in this action. (D.I. 157, Pfizer Opp. at 9). Pfizer also argues that this potential defense and counterclaim by Apotex is speculative. (Id.)

Initially, although Apotex has not specifically pleaded patent misuse to date in this action, Apotex's Thirteenth Affirmative Defense specifically recites: "Any additional affirmative defenses or counterclaims that discovery may reveal." (D.I. 110, Thirteenth Affirmative Defense). If in the course of discovery, information becomes available indicating that a new defense or counterclaim exists, Apotex is fully within its rights to seek leave to amend its Answer to include that defense or counterclaim.

Further, Pfizer characterizes the patent misuse issue as speculative and then proceeds to argue the merits of why it believes it has not misused the '667 patent. In support of its argument

on the merits, Pfizer relies on a Ranbaxy press release, "which explains that the settlement involved multiple unrelated products (e.g., Accupril) and multiple patent disputes worldwide." (D.I. 157, Pfizer Opp. at 10). Pfizer also argues that it is "fanciful to believe that Pfizer, or any other company, would risk losing a multibillion-dollar franchise like Lipitor," and that "this is especially true given that by law the settlement agreements at issue had to be submitted for review to both the Federal Trade Commission and the U.S. Department of Justice. Pfizer's arguments miss the point. Apotex is entitled to discover information, such as the third-party generic atorvastatin agreements, relating to the subject matter of Pfizer's asserted '667 patent in order to evaluate and potentially develop, if appropriate, additional defenses and/or counterclaims that may exist but that Apotex did not know about at the time it answered the First Amended Complaint in this action. Apotex is not required to take Pfizer's word at face value. Quite the contrary, the absurd rationale that Pfizer is touting here is precisely why Apotex is entitled to probe and seek discovery on this issue. That brand-generic settlement agreements have to be submitted to the Federal Trade Commission and Department of Justice for antitrust review further supports Apotex's relevancy arguments—why, after all, would two Federal administrative agencies waste time reviewing settlement agreements if there was never any risk of anticompetitive behavior by the parties to those agreements, as Pfizer suggests? Apotex should be able to view those agreements and judge for itself whether a defense of patent misuse is available to it.

VI. Production of the Third-Party Generic Atorvastatin Agreements Will Not Prejudice Apotex's Generic Competitors.

Pfizer argues that production of the third-party generic atorvastatin agreements will yield Apotex unfair advantage vis-à-vis its generic competitors. (D.I. 157, Pfizer Opp. at 11). This is also pure nonsense. Pfizer's claims of prejudice are unfounded because, as pointed out in

Apotex's opening brief, only Apotex's outside counsel will have access to these third-party generic atorvastatin agreements, and not Apotex itself, and the information will only be used in defense of this action. At oral argument before the Court on July 20, Pfizer argued that inadvertent disclosure by Apotex's litigation counsel was a possibility warranting denial of Apotex's motion. As represented to the Court, counsel for Apotex takes its duty of confidentiality very seriously and will abide by any terms set by the Court on the use of materials order to be produced. Moreover, Pfizer's disingenuous rationale could be used in every case to deny the opposing party highly relevant discovery, which is reason enough for the Court to reject it.

VII. Pfizer misconstrues the plain language of 35 U.S.C. § 271(e)(4).

Pfizer misconstrues the plain language of 35 U.S.C. § 271(e)(4), the infringement remedy provision of the Patent Statute for Hatch-Waxman cases, which sets apart and distinguishes the resetting of any effective approval date for the infringing ANDA from injunctive relief, which "***may be granted against the infringer***." (35 U.S.C. § 271(e)(4)(B)(emphasis added); *cf*. subsec. (A)). Pfizer, not Apotex, has put the injunctive relief provided for by § 271(e)(4)(B) at issue here by including in its First Amended Complaint a request for permanent injunctive relief under this provision. (*See* 09-cv-6053 D.I. 25, First Am. Compl. ¶¶ 51-56 and request for relief ¶ D). Indeed, Pfizer itself appears to fully appreciate the distinction between these two relief provisions of § 271(e)(4), as reflected by the fact that Pfizer's First Amended Complaint includes, in addition to a request for a permanent injunction under § 271(e)(4)(B), a separately delineated paragraph requesting, under § 271(e)(4)(A), that the effective approval of Apotex's ANDA be not earlier than the expiration of the '667 patent. (*See id*. at request for relief ¶ C).

VIII. Given Pfizer's Separate Request for a Permanent Injunction Under 35 U.S.C. § 271(e)(4)(B), the Generic Entry Documents Are Highly Relevant.

In light of Pfizer's request for permanent injunctive relief for infringement of the '667 patent, any documents on Pfizer's anticipated reaction to generic entry are relevant here. If Pfizer is able to establish infringement, it will be required to demonstrate irreparable harm as one of the prerequisites for obtaining permanent injunctive relief under 35 U.S.C. § 271(e)(4)(B). Pfizer argues that such documents will not be relevant because they focus on the period of time after expiration of the '667 patent. (D.I. 157, Pfizer Opp. at 14). Pfizer's attempts at misdirection are transparent. The point is that these documents directly concern the financial implications of generic entry into the market for atorvastatin tablets. The documents, therefore, will be relevant to an assessment of the financial harm to Pfizer that would ensue upon generic entry—whether this occurs before ***or*** after expiration of the '667 patent. *See, e.g., Purdue Pharma L.P. v. Boehringer Ingelheim GmbH,* 237 F.3d 1359, 1368 (Fed. Cir. 2001) (information relating to potential price erosion and loss of market position are relevant to irreparable harm); *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996) (information relating to revenue, goodwill with consumers, and necessary resulting necessary reductions in research and development expenditures are relevant to irreparable harm). Moreover, Apotex is not just seeking projections Pfizer has created for generic entry after expiration of the '667 patent, ***but also any projections Pfizer has created for generic entry before expiration of the '667 patent***. The Court should order production of Pfizer's generic entry documents. *See Orion,* 2010 WL 686545, at *7-8 (granting motion to compel the production of information concerning possible generic market entry scenarios).

CONCLUSION

For the reasons set forth above and the reasons set forth in Apotex's opening brief, Apotex respectfully requests that Pfizer be compelled to produce all documents responsive to Apotex's Request Nos. 114-115 and 122-123, including third-party generic atorvastatin agreements and generic entry documents.

Dated: July 22, 2010.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

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CERTIFICATE OF SERVICE

I, Andrew M. Alul, an attorney, hereby certify that on this 22nd day of July, 2010, a true and correct copy of the foregoing REPLY MEMORANDUM IN SUPPORT OF APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system which will send notification of such filing via electronic mail to all counsel of record.

/s/ Andrew M. Alul

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